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4 510(k) Summary

510(k) Summary of Safety and Effectiveness

Date: August 07, 2001

Submitter: PAR Medizintechnik GmbH
Einemstrasse 9
D-10787 Berlin
Germany

Contact Person: Lothar Engel
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Device: Trade Name: Tonoport V

Common/Usual Name: NIBP Holter System

Classification Names:

21 CFR 870.1130 Non-Invasive Blood-Pressure Measurement System DXN

Predicate Device: K964235 Device Name: ABPM Mobil-o-Graph Blood Pressure Monitor, Model ABP Control

Device Description: The Tonoport V is a compact, lightweight, patient-borne, non-invasive blood pressure (NIBP) holter using the oscillometric method. The cuff is borne on the upper arm and an electrical pump inside the device generates the pressure in the cuff. The Tonoport V is powered from two AA size batteries (alkaline or rechargeable NiMH batteries).
For periods of up to 30 hours it records the patient's blood pressure at predefined intervals and save the results. In order to assess the measurements, the stored data can be transmitted via a RS-232 interface

to a 9-needle dot-matrix printer with serial interface (EPSON LX-300+)

or to another medical device for further evaluation or archiving purposes.

Intended Use: Tonoport V is intended to be used for measuring the systolic, diastolic, mean blood pressure and the heart rate of human beings for periods up to 30 hours. The intended patient populations are adults and children (but not neonates) with a circumference of the upper arm in the range of 17 cm to 42 cm.
Tonoport V is a prescription device in health care medicine. It can be used, if the physical condition of the patient allows an automatic, non-invasive blood pressure measuring under his observation. Medically trained staff like a doctor or nurse, etc should do this judgment as well as the accommodation of the patients and the preparation and application of the Tonoport. The patient does not operate with the

Tonoport V by himself. A measurement with Tonoport V is combined with other measurements and medical examinations at the patient, so that a diagnosis about the patient's health condition depends not alone from the measurement of the Tonoport V.

Technology:

The Tonoport V employs the same functional technology as the predicate device.

Test Summary:

The Tonoport V complies with the voluntary and mandatory standards as detailed in Section 12 of this submission. The following quality assurance measures were applied to the development of the Tonoport V:

- Requirements specification review
- Software and hardware testing
- Safety testing
- Environmental testing
- Final verification and validation
- Compliance with performance standards

Conclusion:

The results of these measurements demonstrated that the Tonoport V is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 9 2001

Mr. Lothar Engel
Technical Manager
PAR Medizintechnik GmbH
Einemstrasse 9
D-10787 Berlin
GERMANY

Re: K012647
Trade Name: Tonoport V
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: August 7, 2001
Received: August 13, 2001

Dear Mr. Engel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012647

NOV 0 9 2001

3 Statement of Indications for Use

Applicant: _____ PAR Medizintechnik GmbH
Einemstrasse 9
D-10787 Berlin
Germany

510(k) Number (if known): _ unknown

Device Name: _____ Tonoport V

The Tonoport V is a compact, lightweight, patient-borne, non-invasive blood pressure (NIBP) holter using the oscillometric method. The cuff is borne on the upper arm and an electrical pump inside the device generates the pressure in the cuff. The Tonoport V is powered from two AA size batteries (alkaline or rechargeable NiMH batteries).
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Tonoport V is not intended to be used in home care medicine or in intensive care medicine or for alarming of life-threatening conditions.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012647